Application Note ▪ Medical

CINCINNATI TEST SYSTEMS
Your Global Leak and Function Test Solution Experts

How to Leak Test Reagent Cartridges

Reagent cartridges contain substances or compounds used to initiate a chemical reaction when exposed to a bio-media. They are most often used for the purposes of infection verification or genetic determination by automated and semi-automated diagnostic (IVD) testing, gene sequencing, and micro-array scanning instrumentation/analyzers. Such devices are commonly found in larger bio-labs or point-of-care facilities such as hospitals or clinics.

Leak tests can be conducted on 100% of these components during production to inspect for leaks within either empty or filled cartridges.

Commonly used names for Reagent Cartridges:

- Reagent Cassettes
- Reagent Kits
- Reagent Reservoirs
- Reagent Pouches
- Reagent Packs

Testing Solutions for Reagent Cartridges/Cassettes

Sentinel Blackbelt

Single channel instrument

Sentinel Blackbelt Pro

Multi-channel instrument with features that support 21 CFR Part 11 and EU Annex 11

Testing 100% of parts in production typically requires dry positive air or nitrogen pressure and/or vacuum leak testing with a single-channel (often multi-port sequential) Sentinel Blackbelt or multi-channel concurrent Blackbelt Pro instrument. Leak testing can be performed both before and after filling the container with reagent. The test processes for both are explained here.

Empty Cartridge Leak Testing

SEALING THE EMPTY CARTRIDGE FOR TEST

1. All openings of the cartridge are sealed with standard CTS CO30/31 or CI30/31 Connects which are designed to seal radially either around the outside (CO30/31) or inside diameter (CI30/31) port(s) of the cartridge.

Depending upon the sealing fixture's design, some automated sealing motions (which do not require two-hand start or extensive safety guarding), may be user-programmed and controlled by optional valves within the instrument. Up to 8 unique motions and their sequence of events may be controlled by a Blackbelt or Blackbelt Pro.

PRESSURIZATION OF THE EMPTY CARTRIDGE

2. The user presses the Start button and the pressure decay leak test cycle begins. The instrument pressurizes the cartridge for a user defined Fill time with regulated compressed air/nitrogen through one or more CTS Connects.

Some cartridges have separate but adjacent internal chambers within them. If there is risk of chamber-to-chamber leaks, adjacent chambers should be pressurized separately—otherwise such leaks could be masked if pressurized simultaneously. Any chambers not currently under test remain vented to the atmosphere.

The pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling detection of improper pressure supply or gross leaks on the cartridge.

STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

3. Once the Fill timer expires, the isolation valve inside the instrument closes, trapping pressure inside the pathway for a user-defined Stabilize time. This time is intended to minimize the natural pressure loss of even non-leaking parts due to expansion or creep, adiabatic thermal effect and potentially absorption, increasing the separation of the final measured pressure loss/decay between good parts and rejects.

The pressure is also measured by the instrument's pressure transducer and compared to min/max limits to detect slightly smaller but still gross leaks on the cartridge chamber being tested.

TEST: DETECTING FINE LEAKS

4. After the Stabilize timer expires, the pressure transducer is tared and the resulting pressure loss/decay is recorded over a user-defined Test time and compared to min/max pressure limits to determine whether fine leaks are present.

EXHAUSTING THE CARTRIDGE CHAMBER(S)

5. Once the Test timer expires, the pressure trapped inside the cartridge or internal chamber is vented to the atmosphere for a user-defined Exhaust time. If the cartridge has multiple adjacent internal chambers, the full test cycle is then repeated for each untested chamber mated to a different test port until all have been individually tested. These sequential tests inspect for both chamber-to-exterior and chamber-to-chamber leakage.

Following the completion of all tests, the CTS Connects release, ending the testing cycle.

Using Leak Rate to Simplify Testing Across Cartridge or Internal Chamber Variations

Many manufacturers opt to convert the basic pressure decay/loss value to a leak rate in standard cubic centimeters per minute (sccm). Because pure pressure loss values are dependent upon the volume under test, similarly-constructed cartridges or their internal chambers which have different pressurized volumes will yield different pressure losses even if they are leaking at the same rate. With a fixed leak rate, larger volumes have lower pressure decay/loss values vs. smaller volume pathways with the same rate of leakage.

The advantage is that once the user defines a target reject leak rate in sccm, they can often apply the same leak rate criteria to an entire family of similar products having differing internal volumes. Executing a simple program calibration teaches the instrument the typical decay of a known non-leaking part alone and then repeated with the same non-leaking part but with a fixed leak standard added. The learning process allows the instrument to accurately convert any future resulting pressure loss to a true leak rate in sccm and make testing parts with unique volumes to have matching reject criteria.

Filled Cartridge Leak Testing

Filled cartridges have unique testing requirements as it is sealed, without possibility of pressurizing or evacuating the interior of non-leaking cartridges. These sealed cartridges require a somewhat consistent internal air headspace volume inside the cartridge or internal chamber at the foil seal to allow accurate dry leak testing.

Instead of positive pressure testing as for empty cartridges, usually all tests are performed with negative pressure (vacuum), which challenges each foil seal by attempting to pull the internal air headspace inside the cartridge out through a leaking foil seal.

SEALING THE FILLED CARTRIDGE FOR TEST

1. All foil sealed openings of the cartridge must be sealed using custom fixturing with sealing heads surrounding each of the foil sealed openings. Alternately, there are applications where sealing around only the foil sealed areas is essentially impossible due to either the part's physical geometry or small cartridge size. If so, the entire cartridge is placed within a custom-made vacuum chamber designed to minimize the external volume surrounding the cartridge exterior to maintain maximum sensitivity during both gross and fine leak tests.

   In either case, the cartridge must be oriented in a manner that allows the entire foil seal to be exposed to the internal trapped air headspace, with no reagent presence contacting the foil seal or leaks may be masked.

EVACUATION OF THE SEALING HEADS OR VACUUM CHAMBER AND GROSS LEAK TEST

2. The user presses the Start button and the pressure decay leak test cycle begins. Because there is only a finite amount of air headspace inside the cartridge above the reagent fill, a gross leak test must first be performed; otherwise, the foil leakage may be so severe that all air headspace is evacuated during a conventional Fill step and no air would later remain to decay during the Test step.

   Within the Blackbelt or Blackbelt Pro instrument, a fixed reference volume is evacuated and its vacuum level compared to min and max limits set by the user. The instrument then releases this vacuum into the sealing heads or test chamber and the instrument's pressure transducer verifies the final delivered vacuum level compared to another set of user-defined limits. If this value is below that minimum vacuum limit, the cartridge is immediately rejected assuming that a gross leak is present on the cartridge, as the vacant headspace inside the test head or chamber is greater than that found on typical sealed parts.

   Typically, the gross leak testing sequence is adjusted by the user such that the final delivered vacuum to the seal heads or vacuum chamber when testing non-gross-leaking parts matches the user's specified fine leak testing vacuum level. Then the test may immediately proceed to the fine leak detection phases.

STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

3. At this point, the isolation valve inside the instrument closes, removing the reference volume from the fine leak test volume

and trapping vacuum inside the seal heads or vacuum chamber for a user-defined Stabilize time. This time is intended to minimize the natural vacuum loss of even non-leaking parts due to expansion or creep, adiabatic thermal effect and potentially absorption, increasing the separation of the final measured loss/decay between good parts and rejects.

The vacuum level is also measured by the instrument's pressure transducer and compared to min/max limits to detect slightly smaller but still gross leaks on the cartridge being tested.

TEST: DETECTING FINE LEAKS

4. After the Stabilize timer expires, the pressure transducer is tared and the resulting vacuum loss/decay is recorded over a user-defined Test time and compared to min/max decay limits to determine whether fine leaks are present.

EXHAUSTING THE SEAL HEADS OR VACUUM CHAMBER

5. Once the Test timer expires, the vacuum trapped inside the seal heads or vacuum chamber is vented to the atmosphere for a user-defined Exhaust time and the user may release the seals or open the vacuum chamber to remove the tested cartridge.

Total test cycle time required is dependent upon many factors, but most critically:

- Reject limit selected
- Volume of the pressurized/evacuated area of the part under test
- For sealed parts, the air headspace volume inside the part
- Temperature stability of part and testing environment
- Dimensional stability of the part while under test
- Repeatability requirements defined by the user
- Accuracy, precision and resolution of the instrument executing the test

Ensuring Failed Parts Are Properly Handled

If using the CTS CO31 Connect controlled by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed cartridges sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release the failed part. This method of forcing the operator to break rhythm limits the risk of failed parts being inadvertently placed for downstream operations with passed cartridges.

Contact CTS to discuss your test application

Contact us for more information on our industry leading medical device leak testing systems for reagent cartridges and other products such as microfluidic cassettes, catheters, medical bags, and tubing sets or to **request a quote today**.

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